Claims

1. A pharmaceutical composition comprising a glucose polymer or a mixture of glucose polymers and, optionally, salts thereof and a non-sensitising bacteriostatic agent.

2. A pharmaceutical composition according to claim 1 wherein the non-sensitising bacteriostatic agent is non-sensitising when applied topically.

3. A pharmaceutical composition according to claim 2 wherein the bacteriostatic agent is non-sensitising when applied intravaginally, rectally or to the penis.

4. A pharmaceutical composition according to claim 1 wherein the bacteriostatic agent is one which possesses both preservative and antimicrobial properties.

5. A pharmaceutical composition according to claim 1 wherein the bacteriostatic agent is effective against Gram positive bacteria, Gram negative bacteria, yeasts and/or moulds.

6. A pharmaceutical composition according to claim 1 wherein the bacteriostatic agent is sorbic acid, or a salt thereof.

7. A pharmaceutical composition according to claim 6 wherein the salt is an alkali metal salt.

8. A pharmaceutical composition according to claim 1 wherein the alkali metal salt is a potassium salt.

9. A pharmaceutical composition according to claim 6 wherein the salt is an alkaline earth metal salt.

10. A pharmaceutical composition according to claim 9 wherein the salt is the calcium salt.

11. A pharmaceutical composition according to claim 6 wherein the sorbic acid, or a salt thereof, is the trans-trans form.

12. A pharmaceutical composition according to claim 1 wherein the bacteriostatic agent may be present in an amount of from 0.01 to 1.0% w/w.

13. A pharmaceutical composition according to claim 12 wherein the bacteriostatic agent is present in an amount of from 0.01 to 0.5 % w/w.

14. A pharmaceutical composition according to claim 13 wherein the bacteriostatic agent is present in an amount of from 0.05 to 0.2% w/w

15. A pharmaceutical composition according to claim 14 wherein the bacteriostatic agent is present in an amount of 0.1% w/w.

16. A pharmaceutical composition according to claim 1 wherein the composition is buffered to vaginal pH.

17. A pharmaceutical composition according to claim 16 wherein the composition is buffered to a pH of from 3.8 to 4.5.

18. A pharmaceutical composition according to claim 16 wherein the buffering agent possesses bacteriostatic properties.

19. A pharmaceutical composition according to claim 16 wherein the buffering agent is lactic acid.

20. A pharmaceutical composition according to claim 16 wherein the buffering agent is present in an amount of from 0.01 to 1.0% w/w.

21. A pharmaceutical composition according to claim 20 wherein the buffering agent is present in an amount of from 0.025 to 0.5% w/w.

22. A pharmaceutical composition according to claim 21 wherein the buffering agent is present in an amount of from 0.05 to 0.2% w/w.

23. A pharmaceutical composition according to claim 22 wherein the buffering agent is present in an amount of from 0.075 to 0.1% w/w.

24. A pharmaceutical composition according to claim 23 wherein the buffering agent is present in an amount of 0.088% w/w.

25. A pharmaceutical composition according to claim 1 wherein the composition is in an aqueous gel form.

26. A pharmaceutical composition according to claim 1 wherein the polyglucose, or a salt thereof, is present in an amount of at least 1 μg/ml.

27. A pharmaceutical composition according to claim 26 characterised in that the polyglucose, or a salt thereof, is present in an amount of from 1 μg/ml to 10^5μg/ml.

28. A pharmaceutical composition according to claim 27 wherein the polyglucose, or a salt thereof, is present in an amount of from 500 μg/ml to 10^5μg/ml.

29. A pharmaceutical composition according to claim 28 wherein the polyglucose, or a salt thereof, is present in an amount of 1×10^4μg/ml.

30. A pharmaceutical composition according to claim 28 wherein the polyglucose, or a salt thereof, is present in an amount of 2×10^4 μg/ml.

31. A pharmaceutical composition according to claim 28 wherein the polyglucose, or a salt thereof, is present in an amount of 4×10^4 μg/ml.

32. A pharmaceutical composition according to claim 1 wherein the composition is made up in unit dosage form comprising from 1 to 10 ml of the composition.

33. A pharmaceutical composition according to claim 32 wherein the composition is made up in unit dosage form comprising from 2 to 5 ml of the composition.

34. A pharmaceutical composition according to claim 1 wherein the glucose polymer or mixture of glucose polymers, and optionally salts thereof, are selected from those polymers described in European Patent Applications Nos. 0 115 991 and 0 153 164.

35. A pharmaceutical composition according to claim 1 wherein the glucose polymer is a salt.

36. A pharmaceutical composition according to claim 1 wherein the salt is an anionic salt.

37. A pharmaceutical composition according to claim 1 wherein glucose polymers are dextrins, or salts thereof.

38. A pharmaceutical composition according to claim 36 wherein the salt is a sulphate.

39. A pharmaceutical composition according to claim 38 wherein the glucose polymer is a dextrin sulphate.

40. A pharmaceutical composition according to claim 39 wherein the dextrin sulphate contains at most two sulphate groups per unit.

41. A pharmaceutical composition according to claim 40 wherein the dextrin sulphate has between 0.5 and 1.5 sulphate groups per unit.

42. A pharmaceutical composition according to claim 41 wherein the dextrin sulphate has up to 1.2 sulphate groups per unit.

43. A pharmaceutical composition according to claim 39 wherein the glucose units of the dextrin are substituted in one or more of the 2, 3 and 6 positions by sulphate groups.

44. A pharmaceutical composition according to claim 43 wherein a substantial proportion of the sulphate groups are in the 2-position.

45. A pharmaceutical composition according to claim 44 wherein greater than 70% of the sulphate groups are in the 2-position.

46. A pharmaceutical composition according to claim 45 wherein more preferably greater than 90% of the sulphate groups are in the 2-position.

47. A pharmaceutical composition according to claim 46 wherein 94% of the sulphate groups are in the 2-position.

48. A pharmaceutical composition according to claim 1 wherein up to 60% by weight of the glucose polymer has a D.P. less than 12.

49. A pharmaceutical composition according to claim 48 wherein the glucose polymer contains at least 50% by weight of glucose polymers of D.P. greater than 12.

50. A pharmaceutical composition according to claim 49 wherein the glucose polymer contains less than 10% by weight of glucose polymers having a D.P. less than 12.

51. A pharmaceutical composition according to claim 50 wherein the glucose polymer contains less than 5% by weight of glucose polymers having a D.P. less than 12.

52. A pharmaceutical composition according to claim 1 wherein the glucose polymer contains little or no material with a high molecular weight.

53. A pharmaceutical composition according to claim 52 wherein the glucose polymer contains little or no material with a molecular weight greater than 40,000.

54. A pharmaceutical composition according to claim 1 wherein dextrin sulphate which contains at most 2 sulphate groups per glucose unit and contains at least 50% of polymers of a degree of polymerisation greater than 12.

55. A pharmaceutical composition according to claim 1 in gel form.

56. A pharmaceutical composition according to claim 55 wherein the gel is administered in a prophylactic device.

57. A pharmaceutical composition according to claim 56 wherein the prophylactic device is a condom.

58. A pharmaceutical composition according to claim 1 wherein the composition comprises an inert carrier or diluent.

59. A pharmaceutical composition according to claim 1 wherein the composition is in powder form.

60. A pharmaceutical composition according to claim 1 wherein the composition is an agent for use in the treatment of HIV-1 and related viruses or other sexually transmitted diseases.

61. A pharmaceutical composition according to claim 1 wherein the composition is adapted to be administered enterally (including orally) or parentally.

62. A pharmaceutical composition according to claim 61 wherein the composition is adapted to be administered parentally.

63. A pharmaceutical composition according to claim 62 wherein the composition is adapted to be administered topically.

64. A pharmaceutical composition according to claim 63 wherein the topical administration comprises administration in, around or on the genitalia, the genito urinary tract and/or the rectum.

65. A pharmaceutical composition according to claim 64 wherein the administration comprises intravaginal administration, penile administration or rectal administration.

66. A pharmaceutical composition according to claim 65 wherein the administration comprises intravaginal administration.

67. A method of treatment, alleviation or prevention of HIV-1 or a related virus or other sexually transmitted diseases by the administration of a composition according to claim 1.

68. A method according to claim 67 wherein the method comprises topical administration.

69. A method according to claim 68 wherein the topical administration comprises administration in, around or on the genitalia, the genito urinary tract and/or the rectum.

70. A method according to claim 69 wherein the method comprises intravaginal administration, penile administration or rectal administration.

71. A method according to claim 69 wherein the method comprises intravaginal administration.

72. A method according to claim 67 which comprises the treatment of any STD or combination of STDs.

73. A method according to claim 72 wherein the STD is one or more of bacterial vaginosis, chlamydia, genital herpes, genital warts, gonorrhoea, syphilis, trichomoniasis, and *Candida*.

74. A method according to claim 67 which comprises administering from 1 to 10 ml of the composition.

75. A method according to claim 74 which comprises administering from 2 to 5 ml of the composition.

76. A method according to claim 67 wherein the polyglucose, or a salt thereof, is present in an amount of at least 1 μg/ml.

77. A method according to claim 76 characterised in that the polyglucose, or a salt thereof, is present in an amount of from 1 μg/ml to 10^5μg/ml.

78. A method according to claim 77 wherein the formulation comprises from 500μg/ml to 10^5μg/ml of the composition.

79. A method according to claim 78 wherein the formulation comprises 1×10^4 μg/ml of the composition.

80. A method according to claim 78 wherein the formulation comprises 2×10^4 μg/ml of the composition.

81. A method according to claim 78 wherein the formulation comprises 4×10^4 μg/ml.

82. A method according to claim 67 which comprises administering a the composition according immediately before or shortly before sexual activity.

83. The use of dextrin sulphates in the manufacture of a composition for the treatment, alleviation or prevention of HIV-1 or a related virus or other sexually transmitted diseases.

84. The use of dextrin sulphates in the manufacture of a composition comprising a glucose polymer or a mixture of glucose polymers and, optionally, salts thereof and a non-sensitising bacteriostatic agent.

85. The use according to claim 84 characterised in that the composition is suitable for the treatment, alleviation or prevention of HIV-1 or a related virus or other sexually transmitted diseases.

86. The use according to claim 85 wherein the composition is suitable for topical administration.

87. The use according to claim 86 wherein the topical administration comprises administration in, around or on the genitalia, the genito urinary tract and/or the rectum.

88. The use according to claim 87 wherein the composition is suitable for intravaginal administration, penile administration or rectal administration.

89. The use according to claim 88 wherein the composition is suitable for intravaginal administration.

90. The use according to claim 85 wherein the composition is suitable for the treatment of any STD or combination of STDs.

91. The use according to claim 90 wherein the STD is one or more of bacterial vaginosis, chlamydia, genital herpes, genital warts, gonorrhoea, syphilis, trichomoniasis, and *Candida*.

92. The use according to claim 85 wherein the treatment, alleviation or prevention comprises administering from 1 to 10 ml of the composition.

93. The use according to claim 92 wherein the treatment alleviation or prevention comprises administering from 2 to 5 ml of the composition.

94. The use according to claim 84 wherein the polyglucose, or a salt thereof, is present in an amount of at least 1 μg/ml.

95. The use according to claim 94 characterised in that the polyglucose, or a salt thereof, is present in an amount of from 1 μg/ml to 10^5μg/ml.

96. The use according to claim 95 wherein the formulation comprises from 500μg/ml to 10^5μg/ml of the composition.

97. The use according to claim 85 wherein the formulation comprises 1 x 10^4 μg/ml of the composition.

98. The use according to claim 85 wherein the formulation comprises 2 x 10^4 μg/ml of the composition.

99. The use according to claim 85 wherein the formulation comprises 4 x 10^4 μg/ml.

100. The use according to claim 85 wherein the treatment, alleviation or prevention comprises administering a the composition according immediately before or shortly before sexual activity.

101. The use of sorbic acid, or a salt thereof, in the manufacture of a composition for the treatment, alleviation or prevention of HIV-1 or a related virus or other sexually transmitted diseases.

102. A composition, method or use, substantially as hereinbefore described with reference to the accompanying description, examples and drawings.